K071020

JUN 1 8 2007

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A Software

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

>GE Healthcare
>86 Pilgrim Road
>Needham, MA 02492 USA
>Tel: 781-449-8685
>Fax: 781-433-1344

NAME OF CONTACT:

>Mr. Joel Kent

DATE:
>March 30, 2007

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

>Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A Software

COMMON NAME:

>Patient Monitor

CLASSIFICATION NAME:

>The following Class II classification appears applicable:

Product Code	Classification Name	CFR Section
MHX	Arrhythmia detector & alarm	870.1025
MLD	Monitor ST-segment & alarm	870.1025
DSF	Paper Chart Recorder	870.2810

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A software is substantially equivalent to the predicate Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software (K022740).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The two software options for the S/5™ Compact Critical Care Monitor are identical, except that the L-CICU05A is equipped with extended arrhythmia analysis capability.

The S/5™ Compact Critical Care Monitor with L-CICU05 and L CICU05A uses several types of plug-in measurement modules. The legacy Datex-Ohmeda M-series or E-series measurement modules are used. Modules are the subject of separate 510(k)'s and are not part of this notification.

The S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A is typically furnished with a module that measures ECG, invasive and non-invasive blood pressures, pulse oximetry and temperature. Modules are placed in the S/5™ Monitor frame and are automatically recognized by the monitor. The patient cables are connected to the module plug in jacks and then monitoring can begin.

The S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A can display measurements in the form of numeric values, traces and trends. Audible and visual alarms are used to indicate patient status. The priority profile of an alarm depends on the parameter.

The S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A is operated by a keyboard. Typically pressing a key results in a pop up menu appearing on the screen. Selections can then be made easily from the menu using a unique ergonomically designed pointing device on the keyboard called a ComWheel™.

The software L-CICU05 and L-CICU05A perform some module related tasks like arrhythmia analysis, ST values calculation, heart rate calculation, impedance and respiration rate calculation, energy expenditure calculation and EEG spectrum analysis evoked potential response averaging calculations. All the module communication is also handled in the main software.

There are various optional types of keyboards, some are like standard keyboards and another is a hand-held Remote controller (K-CREMCO) which is still directly connected to the S/5™ Compact Critical Care Monitor via a long cord but provides more flexibility in controlling the monitor while the doctor or nurse is handling other patient care needs. To facilitate quick access to menus, a bar code reader is also supported, although the bar code reader is not manufactured anymore.

The S/5™ Compact Critical Care Monitor can be in a stand-alone or networked configuration. If networked, measurements are sent to the network for central station or monitor-to-monitor viewing. Trends as well as the patient care documentation can be sent via a network to a central computer for archiving. Networking can be hardwired or wireless.

The S/5 Compact Critical Care Monitor can also be upgraded to L-CICU05(A) software using the S/5 L.I.F.E. upgrade program that offers a means to continuously keeping products up-to-date, by upgrading modular anesthesia and critical care monitors and network products dating from back to 2000 to the latest S/5 software level. Upgrading of modular monitors and network products is performed with one of the available U-LIFE upgrade kits. The kit includes all hardware and software components needed to make the monitor or network product compatible with the latest main software being delivered. The currently available U-LIFE upgrade kit codes for S/5 Compact Critical Care Monitor are:
ULIFE4-00-03 with U-CICU05 and User's Guide
ULIFE4-00-03 with U-CICU05A and User's Guide

INTENDED USE as required by 807.92(a)(5)

Intended Use:

The S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A is intended for multiparameter patient monitoring with optional patient care documentation.

Indications for use:
The S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Bispectral index (BIS), and neurophysiological status of all hospital patients.
The S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A software when using BIS is for monitoring the state of the brain by data acquisition and processing of electroencephalograph signals and may be used as an aid in monitoring the effects of certain anesthetic agents.
The S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A software is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A software is substantially equivalent to the predicate Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software (K022740).
The S/5™ Compact Critical Care Monitor with L-CICU05and L-CICU05A is a modular multiparameter patient monitor providing connections to measurement modules. The general construction, intended use of the S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A are the same as for the predicate S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software (K022740). The indications for use for the Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A software are the same as for the predicate.
The S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Bispectral index (BIS) and neurophysiological status of all hospital patients. The S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A software when using BIS is for monitoring the state of the brain by data acquisition and processing of electroencephalograph signals and may be used as an aid in monitoring the effects of certain anesthetic agents. The S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A software is indicated for use by qualified medical personnel only.
Based on the above and a detailed analysis in Tab 5 Comparison and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of the S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A software is substantially equivalent to the predicate S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software (K022740).

<u>SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by</u>
<u>807.92(b)(1)(3)</u>

The Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A
Software has been assessed against the standards below and details of conformity are presented in
the attached 510(k) notification. The device has been thoroughly tested through validation and
verification of specifications.

- IEC 60601-1:1988+ Amdt.:1:1991 + Amdt. 2:1995
- EN 60601-1: 1990 + A1:1993+A2:1995+A13:1996
- CAN/CSA-C22.2 No.601.1-M90 +S1:1994+Amdt. 2:1998
- IEC 60601-2-27:1994/EN 60601-2-27:1994
- IEC 60601-2-30:1999/EN 60601-2-30:2000
- IEC 60601-2-34:2001/EN 60601-2-34:2000
- IEC 60601-2-40:1998
- IEC 60601-2-49:2001
- IEC 60601-1-2(2001)/EN 60601-1-2
- IEC 60601-1-4: 1996+Amdt. 1:1999/EN 60601-1-4
- ISO 9918:1993/EN 864:1996
- ISO 9919:1992/EN865:1997
- ISO 7767:1997/EN12598:1999
- IEC 601-2-10:1987/EN 60601-2-10:2000 + Amd.1:2001
- IEC 60601-2-26:2002/EN60601-2-26
- EN 1060-1:1995 / EN-1060-3:1997
- EN 12470-4:1992
- IEC 60068-2
- UL 2601-1:1997
- ANSI/AAMI ES-1:1993
- ANSI/AAMI EC57:1998
- FDA 21 CFR 898.12

<u>CONCLUSION:</u>

The summary above shows that the Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-
CICU05 and L-CICU05A Software is substantially equivalent in safety and effectiveness to the
legally marketed (predicate) Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU02
and L-CICU02A software (K022740).

JUN 1 8 2007

GE Healthcare
c/o Mr. Joel C. Kent, RAC
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K071020
    Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU05 and
    CICU05A Software
    Regulation Number: 21 CFR 870.1025
    Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement
    and alarm)
    Regulatory Class: Class II (two)
    Product Code: MHX
    Dated: May 21, 2007
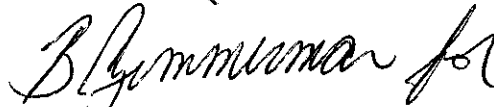   Received: May 21, 2007

Dear Mr Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device
referenced above and have determined the device is substantially equivalent (for the indications
for use stated in the enclosure) to legally marketed predicate devices marketed in interstate
commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to
devices that have been reclassified in accordance with the provisions of the Federal Food, Drug,
and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).
You may, therefore, market the device, subject to the general controls provisions of the Act. The
general controls provisions of the Act include requirements for annual registration, listing of
devices, good manufacturing practice, labeling, and prohibitions against misbranding and
adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA),
it may be subject to such additional controls. Existing major regulations affecting your device
can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA
may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
 Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __K071020__

Device Name: __Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A Software.__

Indications for use:

The S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion, Bispectral index (BIS), and neurophysiological status of all hospital patients.

The S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A software when using BIS is for monitoring the state of the brain by data acquisition and processing of electroencephalograph signals and may be used as an aid in monitoring the effects of certain anesthetic agents.

The S/5™ Compact Critical Care Monitor with L-CICU05 and L-CICU05A software is indicated for use by qualified medical personnel only.

Prescription Use ___X___   AND/OR   Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)   (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number____K071020____